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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,408	09/18/2003	Martin A. Voet	17455CIP1 (BOT)	7456

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,408	VOET, MARTIN A.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~9/18/03~~ 02/25/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Informalities

The disclosure is objected to because of the following informalities:

1. Fig. 2 shows two graphs: a) and b), however, the description of Fig. 2 (at page 15) does not explain these two graphs. Appropriate correction is required. The subtitle "DRAWINGS" should be changed to "Brief Description of the Drawings".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are indefinite because the claims lack essential steps in the method for treating fibromyalgia or fibromyalgia pain. The omitted steps are the method of administration, the location of administration, the effective amount of a botulinum toxin used and/or the outcome of the treatment. Claims 2-5, 7-9 and 11-14 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Borodic (WO 94/15629).

Borodic teaches a method of treating myofascial pain syndrome which includes localized fibromyalgia (page 7, lines 11-12). Specifically, Borodic teaches the administration of botulinum toxin A into the trapezius muscles of a patient having myofascial pain with a needle. See Example 1. These injections reduced pain in the posterior aspect of her skull, down towards mid position of the low back, inner arm and neck. Pain was attenuated for approximately 12 weeks. Therefore, Borodic teaches a method of treating fibromyalgia (claims 1, 10) or fibromyalgia pain (claim 6) by administering intramuscularly via a needle (claims 4, 5, 9 and 13) a therapeutic amount of botulinum toxin A (claims 2, 3, 7 and 8) to a peripheral location (trapezius; claim 11) in a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain (claim 12), and relieving the pain for about 12 weeks. It appears the locus of pain (head and neck) and the peripheral location (trapezius) are anatomically distinct and/or anatomically distant from each other (claim 10).

4. Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by Paulson *et al.* (Movement Disorders 11, 459 (1996)).

Paulson *et al.* teach treating patients with fibromyalgia pain in the shoulders by injecting lidocaine or botulinum toxin alternately, allowing 3 months between injections, where patients were injected with 100 units of botulinum toxin in 2 cc of saline into each of four trigger points

across the trapezius muscle, and among 5 patients, it appears only one patient reported dramatic relief from injection (whole document, Claims 1, 2, 4-7 and 9).

5. Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by Asherson *et al.* (J. Rheumatol. 28 (7), 1740, July 2001).

Asherson *et al.* teach using botulinum toxin A in treating patients with fibromyalgia (FM), where the patients all had numerous FM trigger points affecting the cervical area, upper shoulders, borders of the scapulae, and lower back, as well as medical aspect of knees, and the botulinum toxin A (< 100 units diluted in 10 cc saline) was injected into local trigger points. It was indicated that relief from symptoms after the botulinum toxin A injections lasted a minimum of 16 weeks in all patients (whole document, claims 1-9).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U. S. Patent 6,623,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-14 in the instant application disclose a method for treating fibromyalgia or fibromyalgia

pain, the method comprising administering a botulinum toxin to a patient afflicted with fibromyalgia or fibromyalgia pain, where the botulinum toxin may be injected into a first location, which is anatomically distinct and/or anatomically distant from a second location of fibromyalgia pain. This is obvious variation in view of claims 1-32 of the patent which disclose a method for treating fibromyalgia or fibromyalgia pain, the method comprising administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a patient afflicted with fibromyalgia or fibromyalgia pain, wherein the peripheral location is not a locus of pain, and the site of administration and the locus of pain are located within a same dermatome. Both sets of claims cite a method of treating fibromyalgia or fibromyalgia pain, the method comprising administering a botulinum toxin to a patient afflicted with fibromyalgia or fibromyalgia pain. Thus, claims 1-14 in present application and claims 1-32 in the patent are obvious variations of a method of treating fibromyalgia or fibromyalgia pain, comprising administration of a botulinum toxin.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
August 18, 2005